SEP 3 2002

K021843

APPENDIX E

510(k) SUMMARY
EyeFeel™ Ophthalmic Warmer
Bio-Lipid, Inc.

This 510(k) summary of safety and effectiveness for the EyeFeel™ Ophthalmic Warmer is submitted in accordance with the requirements of SMDA and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	Bio-Lipid, Inc.
Address:	8780 SW 92 Street Suite 203 Miami, FL 33176
Contact Person:	David J. Bloch Regulatory Counsel
Telephone:	(202) 414-9209 (telephone) (202) 414-9209 (fax)
Preparation Date:	May 2002
Device Trade Name:	EyeFeel™
Common Name:	Ophthalmic Warmer
Classification Name:	Hot or Cold Disposable Pack (see 21 C.F.R. § 890.5710) Product Code: IMD
Predicate Devices:	Porta-Warm™ Mattress, 510(k) # K982652 Kwik Heat™ Perineal Warm Pack, 510(k) # K973770
Device Description:	The EyeFeel Ophthalmic Warmer is a simple device for application of heat therapy to the eye. It is shaped as a kind of "mask" to fit over the eyes, and consists of layers of synthetic paper, which surround a "sac" containing an iron powder mixture. Oxidation of the iron powder mixture generates heat.

Intended Use: The EyeFeel™ is a hot disposable pack for the application of localized heat therapy in cases of chronic inflammatory and cystic conditions of the eye lids, including meibomian gland dysfunction and chalazia.

Performance Data: Six patients with noninflamed obstructive MGD tested the EyeFeel Product. Each applied the EyeFeel for 5 minutes. Before and after the heat therapy, the investigators performed the following measurements: (1) a tear evaporation test; (2) a measurement of tear breakup time (BUT), and (3) an assessment of orifice obstruction and meibomian gland (MG) lipid expressibility.

The results are depicted graphically below:

	Prior to Heat Therapy	**Following Heat Therapy**	**P Value**
Tear Evaporation Rate (10^{-7}g cm^{-2} sec^{-1})	6.6+/- 0.97	4.7 +/- 1.5	0.028
BUT (seconds)	3.0+/- 2.1	11.0+/-2.7	0.028
MG lipid expressibility score[1]	2.2+/-0.41	1.0+/-0.0	0.028

Three patients with healthy eyes were examined, to measure the impact of heat treatment on the eyelids and cornea, and confirm the safety of the EyeFeel. The upper and lower eyelid temperature was measured before and after heat therapy using the EyeFeel with the eyes closed. The mean upper and lower eyelid temperatures increased from 34.4+/-0.25°C to 40.0+/-0.38°C and from 34.2+/-0.31°C to 40.4+/-0.10°C respectively. Corneal temperature was measured before and after heat therapy using the EyeFeel with the

[1] Score was based on the following scale:

Grade 0 – clear meibum easily expressed
Grade 1 – cloudy meibum expressed with mild pressure
Grade 2 – cloudy meibum expressed with more than moderate pressure
Grade 3 – meibum cannot be expressed, even with hard pressure

eyes open. The mean corneal temperature increased from 34.0+/-0.86°C to 37.7+/-0.51°C. The temperature difference, pre and post warming, was 3.7+/-1.37°C and 6.1+/-0.25°C.

CONCLUSIONS: Based on the foregoing and other information in this application, Bio-Lipid, Inc. believes that the EyeFeel™ is substantially equivalent to its claimed predicates under conditions of intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 2002

Bio-Lipid Inc.
c/o David J. Bloch
Reed Smith, L.L.P.
1301 K Street, N.W.
Suite 1100
Washington, DC 20005

Re: K021843
Trade/Device Name: EyeFeel Ophthalmic Warmer
Regulation Number: 21 CFR 890.5710
Regulation Name: Hot or cold disposable pack
Regulatory Class: I
Product Code: IMD
Dated: June 5, 2002
Received: June 5, 2002

Dear Mr. Bloch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

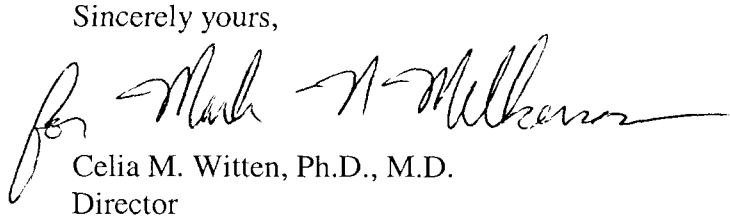
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K021843

Device Name: EyeFeel™ Ophthalmic Warmer

INDICATIONS FOR USE:

The EyeFeel™ Ophthalmic warmer is a hot disposable pack for the application of localized heat therapy in cases of chronic inflammatory and cystic conditions of the eye lids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye, and chalazia.

* * *

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 C.F.R. 801.109)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021843